caBIG™ DSIC Workspace Meeting
Thomas Jefferson University
January 22-23, 2008

DSIC Workspace Meeting DAY 1: Tuesday, January 22, 2008		
7:30 a.m.– 8:30 a.m.	**REGISTRATION & BREAKFAST**	
8:30 a.m. – 8:45 a.m.	**Welcome and Objectives:** **Wendy Patterson, J.D.,** NCI Facilitator for DSIC WS; Senior Advisor, NCI Technology Transfer Center **Richard Pestell, MD, PhD**, Director, Kimmel Cancer Center, Thomas Jefferson University **Jack London, Ph.D.,** Director, Kimmel Cancer Center Informatics Core Facility, Thomas Jefferson University **Agenda Setting:** **Marsha Young, J.D.,** DSIC WS Coordinator, Booz Allen Hamilton - Day 1 Agenda - Day 2 Agenda	
8:45 a.m. – 9:15 a.m.	**DSIC Workspace Update: Summary of May 2007 DSIC Workspace Meeting and subsequent activities – *Where we were, where we are*** **Wendy Patterson, J.D.,** NCI Facilitator for DSIC WS, Senior Advisor, NCI Technology Transfer Center	**PURPOSE:** *Review progress since May meeting and remaining tasks in DSIC Workplan for EY-1 (March 2007 - March 2008)*
9:15 a.m. – 10:45 a.m.	**Building out the Data Sharing and Security Framework (DSSF): Analysis of Legal/Regulatory Restrictions on Data Sharing** **Rachel Nosowsky, J.D.,** Assistant General Counsel, Office of the Vice President and General Counsel, University of Michigan **Marsha Young, J.D.,** DSIC WS Coordinator, Booz Allen Hamilton ○ **Overview**	**PURPOSE:** *Review and gather suggestions for refining, extending and implementing the Framework; lay out strategy for adoption of Framework and metrics for assessing success*

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	○ **Practical Application of the Data Sharing Framework – Consideration of Legal/Regulatory (Privacy and Ethical) Restrictions** ○ Privacy-Based Restrictions: Limitations on data sharing imposed by federal and state privacy laws and institutional policies. ▪ Discussion of DSSF Bundle items that may be helpful in converting data that can be exchanged only in the yellow or orange lanes to data that can be exchanged in the green or yellow lanes. [DeID Paper] ○ Research Policy Restrictions: Limitations on data sharing imposed by the Common Rule, FDA regulations, institutional policies, or informed consent documents. ▪ Discussion of DSSF Bundle items that may be helpful in assuring that data can be exchanged in the green or, if necessary, in yellow lanes. [Guidelines for Preparing Data Sharing Plans] [Standardized Informed Consent Document/Questions] [Researcher questionnaire for assessing data sharing restrictions] ***NOTE**: Security considerations and related DSSF Bundle elements will be addressed later on Day 1; proprietary and contractual restrictions will be addressed in detail on Day 2.*	
10:45 a.m. – 11:00 a.m.	**BREAK**	
11:00 a.m. – 12:30 p.m.	**Implementing the DSSF**	**PURPOSE:** *Discuss terms to be covered and efficient methods of transfer, e.g., use of legally*

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	Rachel Nosowsky, J.D., Assistant General Counsel, Office of the Vice President and General Counsel, University of Michigan **Marsha Young, J.D.,** DSIC WS Coordinator, Booz Allen Hamilton • **Case Study: Applying the Framework to TCGA Data to Identify Legal/Regulatory Barriers to Sharing** • **Using the Guidelines to Develop a Data Sharing Plan** • **Introduction of Terms of Use and Other Agreements Supporting Exchange in the Green, Yellow, and Orange Lanes** ▪ ***Using the "Green lane"*** No contractual relationship between data providers and recipients; general website terms of use for Grid users ▪ ***Using the "Yellow lane"*** Standardized, click-through data use agreements for limited datasets or other moderately sensitive data ▪ ***Using the "Orange lane"*** Standardized data sharing agreements for data sets that require stringent security ***-- OR --*** Guidance for drafting terms and conditions for individually negotiated bilateral or multi-lateral agreements to share high sensitivity data	*enforceable digital signatures*

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12:30 p.m. – 2:00 p.m.	**Working Lunch on site – Update from the NCI-caGrid Security Working Group**	
12:30 p.m. – 2:00 p.m.	**Update from the NCI-caGrid Security Working Group:** ***Description of SWG role, processes and responsibilities of members; summary of short, medium and long term priorities, including consideration of recommendations from Security Policy and Procedures project*** **Moderated by: Daniela Smith, SWG** Coordinator, Booz Allen Hamilton **Panel participants:** **Elaine Brock, J.D.,** Senior Associate Director, Division of Research Development Administration, University of Michigan **George Komatsoulis, Ph.D.,** Director of Quality Assurance, NCI Center for Biomedical Informatics and Information Technology (NCI-CBIIT) **William Weems, Ph.D.,** Assistant Vice President, Academic Technology, Associate Dean of Information Technology, University of Texas Medical School **Frank Manion, M.S.,** Chief Technology Officer and Senior Director, Information Science and Technology Fox Chase Cancer Center	**PURPOSE:** *Summarize the work accomplished since the May F2F and present the major issues to be addressed by the SWG in the coming months and gather perspectives from participants*
2:00 p.m. – 3:30 p.m.	**Efforts to Standardize and Simplify the Informed Consent Process** **Moderated by: Rachel Nosowsky, J.D.,** Assistant General Counsel, Office of the Vice President and General Counsel, University of Michigan **Panel participants:**	**PURPOSE:** *Identify and discuss major impediments to data sharing impacted by informed consent forms and processes, educate DSIC members about various efforts underway nationally, focus in particular on the patient perspective, and roll out prototype "living" documents for use by researchers using the caBIG infrastructure*

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	Cindy Brach, M.P.P., Health Policy Researcher and Project Officer, Agency for Healthcare Research and Quality/DHHS
	Lynn Dressler, Dr. P.H., Assistant Professor, UNC School of Pharmacy, Institute for Pharmacogenomics and Individualized Therapy
	Sarah Greene, M.P.H., Research Associate, Group Health Center for Health Studies
	Deborah Collyar, Patient Advocates in Research
	Mary Lou Smith, Research Advocacy Network
	
	• **Review of the Summary Document**
	• **Introduction of Representative Projects**
	  ○ PRISM
	  ○ GBC
	  ○ AHRQ
	• **Patient Concerns**
	• **Roll-Out of the *draft* DSIC Template**
	  ○ WS-Wide Input Solicited to 2/1
	  ○ Final Draft to OHRP for Comment	

3:30 p.m. – 3:45 p.m.	**BREAK**	
3:45 p.m. – 4:30 p.m.	**Update on caBIG Enterprise Support Network** **Leslie Derr, Ph.D.,** Director of Community Alliances & Support, NCI CBIIT	**PURPOSE:** *Inform group of structure of ESN and expected role of DSIC Workspace*
4:30 p.m. – 5:30 p.m.	**Questions from representatives of "Getting Connected" Centers and NCCCP Centers**	**PURPOSE:** *Address questions of newcomers to caBIG DSIC Workspace*

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DSIC WORKSPACE DAY 2: Wednesday, January 23, 2008		
7:30 a.m. – 8:30 a.m.	**Breakfast**	
8:30 a.m. – 8:40 a.m.	**Welcome and Agenda Setting:** **Marsha Young, J.D.,** DSIC WS Coordinator, Booz Allen Hamilton -Day 2 Agenda	
8:40 a.m. – 8:45 a.m.	**Introduction of Keynote Speaker: Ken Buetow, Ph.D.:** **Wendy Patterson, J.D.,** NCI Facilitator for DSIC WS; Senior Advisor, NCI Technology Transfer Center	
8:45 a.m. – 9:45 a.m.	**Keynote Address:** **Ken Buetow, Ph.D.** NCI Associate Director for Biomedical Informatics and Information Technology Director, NCI Center for Biomedical Informatics and Information Technology (NCI CBIIT)	**PURPOSE:** *Present the caBIG™ program management's perspective on achievements and vision for the program in Enterprise Year 2 and beyond. Update the charge to the DSIC Workspace in the coming year in light of program directions.*
9:45 a.m. – 10:45 a.m.	**Update from the other caBIG™ Workspaces:** ***What are the agendas of the other caBIG Workspaces in the coming year? How can the DSIC WS support the needs of the caBIG Workspaces? How will the respective WS work plans be integrated?*** **Moderated by: Marsha Young, J.D.,** DSIC WS Coordinator, Booz Allen	**PURPOSE:** *Understand the projects planned for this year by the other Workspaces and determine coordination needs as well as DSIC support requirements*

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	Hamilton **Panel participants:** **Clinical Trials Management Systems (CTMS): John Speakman,** Associate Director, Clinical Trials Products and Programs, NCI CBIIT **Tissue Banks and Pathology Tools (TBPT): Ian Fore, Ph.D.,** Associate Director, Biorepository and Pathology Informatics, NCI CBIIT **Integrative Cancer Research (ICR): Elaine Freund, Ph.D.,** Integrative Cancer Research WS Coordinator, Booz Allen Hamilton **In Vivo Imaging (IMAG): Paul Mulhern, Ph. D.,** In Vivo Imaging WS Coordinator, Booz Allen Hamilton **Vocabulary & Common Data Elements (VCDE)/Architecture (ARCH): Mike Keller,** Architecture WS Coordinator, Booz Allen Hamilton**)** **Documents and Training (D&T): Jenny Ticker,** Documentation and Training WS Coordinator, OKA	
10:45 a.m. – 11:00 a.m.	**BREAK**	
11:00 a.m. – 12:30 p.m.	**Roundtable: Addressing the Proprietary and Contractual Restrictions on caBIG-enabled Data Sharing** **Framing the Issues** **Elaine Brock, J.D.,** Senior Associate Director, Division of Research Development Administration, University of Michigan **Session I: Experiences in the Field - *Actual and anticipated challenges/needs associated with sharing data via the caBIG™ infrastructure: Perspectives of caBIG adopters, academic researchers and participants in the drug discovery/development process***	**PURPOSE:** *Articulate the challenges that adopters and end users are likely to encounter in using the caBIG infrastructure; specify requirements for support*

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	Moderated by DSIC WS Patient Advocates: Mary Lou Smith, Research Advocacy Network, and **Deborah Collyar,** Patient Advocates in Research (PAIR) **Panel participants:** ▪ **Jack London, Ph.D.,** Director, Kimmel Cancer Center Informatics Core Facility, Thomas Jefferson University ▪ **Warren Kibbe,** Ph.D., Technical Director of Research Computing, Basic Sciences ▪ **Subha Madhavan, Ph.D.,** NCI CBIIT Director for Integrative Cancer Research ▪ **Jill Sorensen, J.D.,** Bilyan, LLC ▪ **Chris Yochim, Ph.D.,** Associate Director, External Relations Strategic Planning Business Development, AstraZeneca Pharmaceuticals, LP ▪ **Tom Neyarapally, J.D.,** Gene Network Sciences	
12:30 p.m. – 1:45 p.m.	**Working Lunch on site – Continuation of Proprietary and Contractual Restrictions Discussion**	

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1:45 p.m. – 3:30 p.m.	**Session II: Reactors' Panel:** ***Discussion and consolidation of themes heard during Session I; identify solutions or pathways thereto, both short term and long term*** **Moderated by: Melissa Markey, J.D.,** Hall, Render, Killian, Heath & Lyman, P.C. **Participants:** ▪ **Dan Mazella, J.D.,** Corporate Attorney, Applera Corporation, Applied Biosystems Group/Celera Group ▪ **Greg Simon, J.D.,** President, Faster Cures ▪ **O. Prem Das, Ph.D.,** technology development consultant ▪ **Richard A. Lambert, J.D.,** intellectual property consultant ▪ **Beth Schermer, J.D.,** Partner, Coppersmith Gordon Schermer Owens & Nelson, PLC ▪ **Allen Tien, M.D., Ph.D.,** President, mdLogix ▪ **John Wilbanks,** Executive Director, Science Commons	**PURPOSE:** *Convey broad expert perspectives on approaching the issues presented during Session I; describe possible solutions; propose revisions to current DSIC work plan/ identify new activities; establish logical sequence and timeline for next steps coming out of this session.*
3:30p.m. - 3:45 p.m.	**BREAK**	
3:45 p.m. – 4:30 p.m.	**Recalibrating the DSIC Workplan** **Moderator: Marsha Young, J.D.,** DSIC WS Coordinator, Booz Allen Hamilton **Participants: All DSIC Workspace members** ▪ Revise existing action items ▪ List of new action items -- new items in DSIC Toolkit? ▪ Set timelines ▪ Enlist participants ▪ Next steps	**PURPOSE:** *Update DSIC EY 2 Workplan and agree on implementation process*

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12:30 p.m. – 2:00 p.m.	**Update from the NCI-caGrid Security Working Group:** ***Description of SWG role, processes and responsibilities of members; summary of short, medium and long term priorities, including consideration of recommendations from Security Policy and Procedures project*** **Moderated by: Daniela Smith, SWG** Coordinator, Booz Allen Hamilton **Panel participants:** **Elaine Brock, J.D.,** Senior Associate Director, Division of Research Development Administration, University of Michigan **George Komatsoulis, Ph.D.,** Director of Quality Assurance, NCI Center for Biomedical Informatics and Information Technology (NCI-CBIIT) **William Weems, Ph.D.,** Assistant Vice President, Academic Technology, Associate Dean of Information Technology, University of Texas Medical School **Frank Manion, M.S.,** Chief Technology Officer and Senior Director, Information Science and Technology Fox Chase Cancer Center	**PURPOSE:** *Summarize the work accomplished since the May F2F and present the major issues to be addressed by the SWG in the coming months and gather perspectives from participants*

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	Panel participants:
	Cindy Brach, M.P.P., Health Policy Researcher and Project Officer, Agency for Healthcare Research and Quality/DHHS
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	• **Review of the Summary Document**
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12:30 p.m. – 2:00 p.m.	**Working Lunch on site – Update from the NCI-caGrid Security Working Group**	
12:30 p.m. – 2:00 p.m.	**Update from the NCI-caGrid Security Working Group:** ***Description of SWG role, processes and responsibilities of members; summary of short, medium and long term priorities, including consideration of recommendations from Security Policy and Procedures project*** **Moderated by: Daniela Smith, SWG** Coordinator, Booz Allen Hamilton **Panel participants:** **Elaine Brock, J.D.,** Senior Associate Director, Division of Research Development Administration, University of Michigan **George Komatsoulis, Ph.D.,** Director of Quality Assurance, NCI Center for Biomedical Informatics and Information Technology (NCI-CBIIT) **William Weems, Ph.D.,** Assistant Vice President, Academic Technology, Associate Dean of Information Technology, University of Texas Medical School **Frank Manion, M.S.,** Chief Technology Officer and Senior Director, Information Science and Technology Fox Chase Cancer Center	**PURPOSE:** *Summarize the work accomplished since the May F2F and present the major issues to be addressed by the SWG in the coming months and gather perspectives from participants*

2:00 p.m. – 3:30 p.m.	**Efforts to Standardize and Simplify the Informed Consent Process**
	
	Moderated by: Rachel Nosowsky, J.D., Assistant General Counsel, Office of the Vice President and General Counsel, University of Michigan
	
	Panel participants:
	Cindy Brach, M.P.P., Health Policy Researcher and Project Officer, Agency for Healthcare Research and Quality/DHHS
	Lynn Dressler, Dr. P.H., Assistant Professor, UNC School of Pharmacy, Institute for Pharmacogenomics and Individualized Therapy
	Sarah Greene, M.P.H., Research Associate, Group Health Center for Health Studies
	Deborah Collyar, Patient Advocates in Research
	Mary Lou Smith, Research Advocacy Network
	
	• **Review of the Summary Document**
	• **Introduction of Representative Projects**
	  ○ PRISM
	  ○ GBC
	  ○ AHRQ
	• **Patient Concerns**
	• **Roll-Out of the *draft* DSIC Template**
	  ○ WS-Wide Input Solicited to 2/1
		PURPOSE: *Identify and discuss major impediments to data sharing impacted by informed consent forms and processes, educate DSIC members about various efforts underway nationally, focus in particular on the patient perspective, and roll out prototype "living" documents for use by researchers using the caBIG infrastructure*

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	○ Final Draft to OHRP for Comment	
3:30 p.m. – 3:45 p.m.	**BREAK**	
3:45 p.m. – 4:30 p.m.	**Update on caBIG Enterprise Support Network** **Leslie Derr, Ph.D.,** Director of Community Alliances & Support, NCI CBIIT	**PURPOSE:** *Inform group of structure of ESN and expected role of DSIC Workspace*
4:30 p.m. – 5:30 p.m.	**Questions from representatives of "Getting Connected" Centers and NCCCP Centers**	**PURPOSE:** *Address questions of newcomers to caBIG DSIC Workspace*

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DSIC WORKSPACE DAY 2: Wednesday, January 23, 2008		
7:30 a.m. – 8:30 a.m.	**Breakfast**	
8:30 a.m. – 8:40 a.m.	**Welcome and Agenda Setting:** **Marsha Young, J.D.,** DSIC WS Coordinator, Booz Allen Hamilton -Day 2 Agenda	
8:40 a.m. – 8:45 a.m.	**Introduction of Keynote Speaker: Ken Buetow, Ph.D.:** **Wendy Patterson, J.D.,** NCI Facilitator for DSIC WS; Senior Advisor, NCI Technology Transfer Center	
8:45 a.m. – 9:45 a.m.	**Keynote Address:** **Ken Buetow, Ph.D.** NCI Associate Director for Biomedical Informatics and Information Technology Director, NCI Center for Biomedical Informatics and Information Technology (NCI CBIIT)	**PURPOSE:** *Present the caBIG™ program management's perspective on achievements and vision for the program in Enterprise Year 2 and beyond. Update the charge to the DSIC Workspace in the coming year in light of program directions.*
9:45 a.m. – 10:45 a.m.	**Update from the other caBIG™ Workspaces:** ***What are the agendas of the other caBIG Workspaces in the coming year? How can the DSIC WS support the needs of the caBIG Workspaces? How will the respective WS work plans be integrated?*** **Moderated by: Marsha Young, J.D.,** DSIC WS Coordinator, Booz Allen Hamilton **Panel participants:** **Clinical Trials Management Systems (CTMS): John Speakman,** Associate Director, Clinical Trials Products and Programs, NCI CBIIT **Tissue Banks and Pathology Tools (TBPT): Ian Fore, Ph.D.,** Associate Director, Biorepository and Pathology Informatics, NCI CBIIT **Integrative Cancer Research (ICR): Elaine Freund, Ph.D.,** Integrative Cancer Research WS Coordinator, Booz Allen Hamilton **In Vivo Imaging (IMAG): Paul Mulhern, Ph. D.,** In Vivo Imaging WS Coordinator, Booz Allen Hamilton **Vocabulary & Common Data Elements (VCDE)/Architecture (ARCH): Mike Keller,** Architecture WS Coordinator, Booz Allen Hamilton**)** **Documents and Training (D&T): Jenny Tucker,** Documentation and Training WS Coordinator, OKA	**PURPOSE:** *Understand the projects planned for this year by the other Workspaces and determine coordination needs as well as DSIC support requirements*

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10:45 a.m. – 11:00 a.m.	**BREAK**	
11:00 a.m. – 12:30 p.m.	**Roundtable: Addressing the Proprietary and Contractual Restrictions on caBIG-enabled Data Sharing** **Framing the Issues** **Elaine Brock, J.D.,** Senior Associate Director, Division of Research Development Administration, University of Michigan **Session I: Experiences in the Field - *Actual and anticipated challenges/needs associated with sharing data via the caBIG™ infrastructure: Perspectives of caBIG adopters, academic researchers and participants in the drug discovery/development process*** **Moderated by DSIC WS Patient Advocates: Mary Lou Smith,** Research Advocacy Network, and **Deborah Collyar,** Patient Advocates in Research (PAIR) **Panel participants:** ▪ **Jack London, Ph.D.,** Director, Kimmel Cancer Center Informatics Core Facility, Thomas Jefferson University ▪ **Warren Kibbe,** Ph.D., Technical Director of Research Computing, Basic Sciences ▪ **Subha Madhavan, Ph.D.,** NCI CBIIT Director for Integrative Cancer Research ▪ **Jill Sorensen, J.D.,** Bilyan, LLC ▪ **Chris Yochim, Ph.D.,** Associate Director, External Relations Strategic Planning Business Development, AstraZeneca Pharmaceuticals, LP ▪ **Tom Neyarapally, J.D.,** Gene Network Sciences	**PURPOSE:** *Articulate the challenges that adopters and end users are likely to encounter in using the caBIG infrastructure; specify requirements for support*
12:30 p.m. – 1:45 p.m.	**Working Lunch on site – Continuation of Proprietary and Contractual Restrictions Discussion**	

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1:45 p.m. – 3:30 p.m.	**Session II: Reactors' Panel:** ***Discussion and consolidation of themes heard during Session I; identify solutions or pathways thereto, both short term and long term*** **Moderated by: Melissa Markey, J.D.,** Hall, Render, Killian, Heath & Lyman, P.C. **Participants:** ▪ **Dan Mazella, J.D.,** Corporate Attorney, Applera Corporation, Applied Biosystems Group/Celera Group ▪ **Greg Simon, J.D.,** President, Faster Cures ▪ **O. Prem Das, Ph.D.,** technology development consultant ▪ **Richard A. Lambert, J.D.,** intellectual property consultant ▪ **Beth Schermer, J.D.,** Partner, Coppersmith Gordon Schermer Owens & Nelson, PLC ▪ **Allen Tien, M.D., Ph.D.,** President, mdLogix ▪ **John Wilbanks,** Executive Director, Science Commons	**PURPOSE:** *Convey broad expert perspectives on approaching the issues presented during Session I; describe possible solutions; propose revisions to current DSIC work plan/ identify new activities; establish logical sequence and timeline for next steps coming out of this session.*
3:30p.m. - 3:45 p.m.	**BREAK**	
3:45 p.m. – 4:30 p.m.	**Recalibrating the DSIC Workplan** **Moderator: Marsha Young, J.D.,** DSIC WS Coordinator, Booz Allen Hamilton **Participants: All DSIC Workspace members** ▪ Revise existing action items ▪ List of new action items -- new items in DSIC Toolkit? ▪ Set timelines ▪ Enlist participants ▪ Next steps	**PURPOSE:** *Update DSIC EY 2 Workplan and agree on implementation process*

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